

510(k) Summary

FEB - 4 2004

K032857

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Date of Summary Preparation:

April 21, 2003

Manufactures Contact Person:

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Colin Medical Instruments Corp.
5850 Farinon Drive
San Antonio, TX. 78249

Trade Name:

Press-Mate BX-10 Vital Signs Monitor

Classification Name, Classification Number, Class, Classification Reference:

Classification Name	Class Number	Class	21CFR§
Pulse rate monitor	74BWS	II	870.2300
Blood pressure computer	DSK	II	870.1110
Non-indwelling blood pressure monitor	74DXN	II	870.1130
Blood pressure alarm		II	870.1100
Pulse Oximeter	74 DQA	II	870.2700
Finger Oximeter		II	
Paper chart Recorder		II	870.2810

Special Controls: There are no regulatory standards or special controls applicable for this device, however, the device voluntarily adheres to the U.S. FDA Guidance Document "NON-INVASIVE BLOOD PRESSURE (NIBP) MONITOR, Version 1.0, dtd. March, 1997 and ANSI/AAMI SP10-1992.

Indications for Use: The Press-Mate BX-10 patient monitor is intended to monitor a single patient's vital signs in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or in an environment where patient care is provided by qualified healthcare personnel who will determine when use of this device is indicated, based upon their professional assessment of the patient's medical condition. The patient populations include adult, pediatric and neonatal. The device capable of monitoring:

Pulse rate (via oximetry data)

Non-invasive pressure (systolic, diastolic and mean oscillometric NIBP)

Blood oxygen saturation (SpO2 via finger oximeter)

This device is intended for use by qualified healthcare personnel trained in its use.

Device Description: The Press-Mate BX-10 Series Monitor is a fully portable multiparameter monitoring device which provides the capability for noninvasive monitoring of adult, pediatric and neonatal patients in numerous hospital, nursing home and clinical settings. It is a prescription device intended for use only by health care professionals. The oscillometric method, upper arm measurement is employed. The Press-Mate BX-10 is configurable with Nellcor® oxygen saturation (Pulse Oximetry) utilizing the finger for the placement of the sensor. The monitor uses a single tube reusable cuff or may be optionally used with a disposable single tube cuff.

The Press-Mate BX-10 has an optional replaceable and rechargeable battery as well as an optional thermal printer to print displayed data, waveforms and trend information. A liquid crystal display (LCD) and (LED) provides high visibility and clarity in most light conditions. The available parameters displayed will depend on the mode selected by the user.

Visual and audible alarms are provided to alert the user to monitor operational conditions or should patient values exceed default or operator-set high/low limits.

Model BX-10: Non-Invasive Blood Pressure and Pulse Rate

Model BX-10-An: Non-Invasive Blood Pressure and Pulse Rate; and Nellcor® Pulse Oximetry.

This portable device includes an optional integrated printer and is capable of operation from an external AC power source or an internal rechargeable battery. The device uses the same technology and materials as the predicate devices, the Press – Mate 8800 (K890876 cleared 6/22/89), Press – Mate Advantage (K 973637 cleared 9/25/98) and the Press-Mate Prodigy (K022537 cleared 9/13/02)

The following accessories are available for use with the device:

1. Power cord
2. Printer Paper
3. Operations Manual
4. Disposable cuffs
5. Reusable cuffs
6. Cuff extension hose
7. Finger Probe
8. Extension Cable

Substantially Equivalent Commercially Available Devices: The Press-Mate BX-10 Monitor is substantially equivalent to the following commercially available predicated devices with respect to indications for use, device design, materials, and method of manufacture.

Colin Corporation, Press-Mate 8800 Monitor	(K890876; K921048C; K942871)
Colin Corporation, Press-Mate Advantage Monitor	(K973637)
Colin Medical Instruments, Press-Mate Prodigy(PM-2100)	(K022537)

Substantial Equivalence Comparison: The Press-Mate BX-10 is similar to commercially available devices with respect to intended use, material, design and operation principles as follows:

1. Operational Principles: the basic operational principles of the Press-Mate BX-10 monitor and the predicate devices are to provide an indication of a patient's vital signs and provide an indication, usually via an alarm, when parameters fall outside of preset limits. The parameters that are measured and displayed are the same as those for the predicate devices.
2. Indications and Contraindications: Relative indications and contraindications for the Press-Mate BX-10 monitor and commercially available devices for similar intended uses are the same.

Assessment of non-clinical performance data for equivalence: Currently there are no FDA standards for this device. However, the Press-Mate BX-10 complies with:

IEC 60601-1-1:2000 19. Electrical Safety
 IEC 60068-2-6:1995; IEC 60068-2-64:1993; IEC 60068-2-27:1987 Shock & Vibration
 EN 865: 1997 Oximetry
 EN 1060-1: 1995 Oscillometry
 EN 1060-3: 1997 Oscillometry
 EN 475: 1995 Sounds & Alarms
 EN 1060-3; 1997 Blood Pressure Monitors- Storage, Temperature and Relative Humidity

Clinical and Bench Testing

Non – Invasive Blood Pressure (NIBP)

For NIBP performance, Colin used ANSI/AAMI SP10-1992: "Electronic or automated sphygmomanometers" and ANSI/AAMI SP10A-1996: Amendment to ANSI/AAMI SP10-1992: American National Standard for Electronic or Automated Sphygmomanometers.

To evaluate environmental performance, Colin met the requirements contained in the November 1993 Draft Reviewer Guidance for Pre-market Notification Submissions of the Anesthesiology and Respiratory Devices Branch of the Division of Cardiovascular, Respiratory, and Neurological Devices.

Clinical Study for Accuracy-Overall System Efficacy:

Accuracy of the NIBP algorithm was established in the adult, pediatric, and neonatal populations with the ANSI/AAMI SP10 clinical study for the Press – Mate 8800 and the Press – Mate Advantage monitors

The NIBP parameter of the new monitor has the same NIBP algorithm that calculates blood pressure from measured oscillations as the Press – Mate 8800 (K890876), Press-Mate Prodigy(PM-2100) (K022537) and the Press – Mate Advantage (K973637). Also, an accuracy study was performed on the new monitor according to AAMI SP – 10 in which 85 adult and pediatric subjects were tested.

Moreover, the NIBP parameter of the new monitor has the same intended use and labeling claims as the Press – Mate 8800 and the Press – Mate Advantage; the same software runs in the same processor family under the same operating system with the same programmer as the predicate device; and the same accessories-air hoses and blood pressure cuffs.

Bench Testing, ANSI/AAMI SP10

The new device was subject to IEC and EN testing to meet the equivalent requirements of ANSI/AAMI SP10 bench testing requirements, including:

- Stability: 4.2.4.1 Voltage Range; and 4.2.4.2 Life
- Safety Requirements: 4.3.1.1 Maximum Cuff Pressure; 4.3.2 Cuff Deflation; 4.3.2 Electrical Safety; and 4.3.3 Conductive Components
- Performance Requirements: 4.4.1 Pressure Indicator Accuracy; and 4.4.3 Battery-Powered Devices.

The new device passed all tests.

Conclusion: In accordance with the Federal Food, Drug and Cosmetic Act and 12 CFR Part 807, and based on the information provided in this premarket notification, Colin Medical Instruments concludes that the new device, the Press-Mate BX-10 monitor is safe, effective and substantially equivalent to the predicate device as described herein.

Press-Mate 8800 & Press-Mate Advantage vs. BX-10

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	BP-8800	Advantage	BX-10
Algorithm	Peak Integral	Peak Integral	Peak Integral
Source Code	C	C	C
CPU	Hitachi 6303,8-bit	Toshiba 301, 16-bit	Hitachi H85/2329-16bit
Programmer	Mr. Yokozeki	Mr. Yokozeki	Mr. Yokozeki
Pump	DC12V	DC12V	DC12V
Bleed/Dump Valve	Combined	Combined	Combined

Clinical testing on the Press-Mate 8800 and data collection and reporting of that data followed the standards described in the ANSI/AAMI-AP-10 1992 “American National Standards for Electronic or Automated Sphygmomanometers”. A total of 85 adults, 85 pediatrics and 15 neonates were evaluated at Baylor College of Medicine under IRB approval with informed consent.

Also, since the Press-Mate Prodigy (PM-2100) displays mean blood pressure, it was also evaluated against arterial line as a reference standard in accordance with FDA recommendations. These tests were performed at the University of Tennessee Medical Center under IRB approval with informed consent.

Three separate monitors were used to determine inter-device variability. The results of the tests are included in Appendix L section e. The device successfully met AAMI SP-10 1992 Standards for accuracy.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Colin Medical Instruments Corp.
c/o Mr. Robert Mosenkis
President
CITECH
5200 Butler Pike
Plymouth Meeting, PA 19462-1298

Re: K032857
Trade Name: Press-Mate Vital Sign Monitor, Models BX-10 and BX-10An
Regulation Number: 21 CFR 870.1130 and 870.2700
Regulation Name: Noninvasive Blood Pressure Measurement System and Oximeter
Regulatory Class: Class II (two)
Product Code: 74 DXN and 74 DQA
Dated: January 19, 2004
Received: January 20, 2004

Dear Mr. Mosenkis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.


Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



 Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K032857

Device Name: Vital Sign Monitor, Patient Monitor; including the following parameters:

Pulse Oximetry (SPO₂)

Non-invasive Systolic, Mean & Diastolic Blood Pressure Measurement (NIBP)

Indications For Use:

The device labeling will indicate:

The Press-Mate BX-10 and BX-10An are indicated for use on adult, pediatric, and neonatal patients by a trained and qualified healthcare professional in the hospital, outpatient surgery practitioner facilities, or in an environment where patient care is provided by qualified healthcare personnel who will determine when use of this device is indicated, based upon their professional assessment of the patient's medical condition.

The Press-Mate BX-10 patient monitor is intended to monitor a single patient's non-invasive blood pressure and pulse rate.

The Press-Mate BX-10An patient monitor is intended to monitor a single patient's non-invasive blood pressure as well as blood oxygen saturation and pulse rate via Nellcor's oximetry technology.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diana R. Lochner
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K032857